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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,367	10/24/2003	Audrey Minden	0575/55311-AZ-PCT-US	2322

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EXAMINER	
SZPERKA, MICHAEL EDWARD	
ART UNIT	**PAPER NUMBER**
1644	

DATE MAILED: 04/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/693,367	MINDEN, AUDREY	
	Examiner	Art Unit	
	Michael Szperka	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 January 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *65 and 67-71* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65 and 67-71* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

jlr

DETAILED ACTION

1. Applicant's response received January 18, 2005 is acknowledged.

Claims 1-64 and 66 are cancelled

Claims 69-71 have been added.

Claims 65 and 67-71 are pending and under consideration in this Office action.

Response to Arguments

Applicant's amendment to the first line of the specification to update the status of priority documents is acknowledged and appreciated.

Claim Rejections - 35 USC § 101

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The rejection of claims 65-68 has been withdrawn due to the amendment of base claim 65 to recite a purified antibody. Note that claim 66 has been cancelled.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The rejection of claims 65-68 under 35 USC 112, second paragraph for being indefinite has been removed due to applicant's amendment to base claim 65 to insert the word "specifically". Note that claim 66 has been cancelled.

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65, 67, and 68 stand rejected and new claims 69-71 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention for the reasons made of record in the Office action mailed October 18, 2004.

Applicant's arguments filed January 18, 2005 have been fully considered but they are not persuasive.

Claims 65, 67 and 68 were rejected as lacking adequate written description under 35 U.S.C. 112, first paragraph because the breadth of applicant's claims originally read upon antibodies that bound all mammalian PAK4 kinases, as well as allelic variants, analogs, fragments, or derivatives of mammalian PAK4 kinases. The

disclosure provided by applicant contains an 89 amino acid partial sequence of mouse PAK4 (SEQ ID NO: 14), the full-length sequence of human PAK4 (SEQ ID NO: 2), a deletion mutant that lacks the GTPase binding domain, and the human point mutants K(350)M, S(474)M and S(474)E. Applicant has amended the claims to replace "mammalian" with either "human" (claims 65, 67, and 68) or "mouse" (claims 69-71). As such, applicant has argued on pages 5 and 6 of the reply received on January 18, 2005 that the rejection should be withdrawn since the scope of the claims has been narrowed.

This argument has been considered but is not found persuasive. The scope of the claims has been narrowed by Applicant's amendment. However, the broadest reasonable interpretation of "A purified antibody capable of specifically binding to a human (mouse) PAK4 serine/threonine kinase" still reads on all allelic variants, analogs, fragments, or derivatives of human (mouse) PAK4. The specification does not define human PAK4 as being limited to SEQ ID NO:2, and indeed PAK4 molecules that differ from the disclosed sequences are disclosed as being part of the invention (see particularly page 13, lines 20-37, page 14, lines 13-38 and page 15, lines 1-16). As indicated above, the only allelic variants, analogs, fragments, or derivatives of PAK4 disclosed by applicant are non-naturally occurring mutant sequences of human PAK4 and a fragment of mouse PAK4. As indicated in the previous office action

"...other than for the already indicated deletion and point mutants, the structure and properties of these PAK4 analogs, fragments, and derivatives are not disclosed, nor is it disclosed how the structures of PAK4 analogs, fragments, and derivatives relate to

their functional properties. As such, the variation in structure and functional properties of such a genus of molecules is substantial."

Given that there is substantial variation in PAK4 molecules of the instant application, the variation in the genus of antibodies that bind such molecules is the same or greater. Since there is high variability amongst the genus of antibodies of the claimed invention, and Applicant has disclosed only a limited amount of the genus of molecules bound by said antibodies, the claimed invention does not have written support within the originally filed specification. Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, § 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, which make clear that if a claimed genus does not show actual reduction to practice for a representative number of species, then the Requirement may be alternatively met by reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 65, 67 and 68 stand rejected and newly added claims 69-71 are rejected under 35 U.S.C. 102(e) as being anticipated by Plowman et al., U.S. Patent Application Publication No. US 2003/0050230 (of record, see entire document) as evidenced by Goldsby et al. (Immunology, 5th edition, pages 62-67) for the reasons of record set forth in the Office action mailed October 18, 2004.

Applicant's arguments on pages 6 and 7 of the response filed January 18, 2005 have been fully considered but they are not persuasive.

Plowman et al. disclose two polypeptide sequences identified as PAK5, one partial sequence (SEQ ID NO: 30 of Plowman et al., 398 amino acids long) and one full-length sequence (SEQ ID NO: 103 of Plowman et al., 591 amino acids long). The 398 amino acid sequence is 100% identical to SEQ ID NO:2 (571 amino acids long), while SEQ ID NO:2 is 100% identical to the 591 amino acid sequence of Plowman et al. Plowman et al. also claim an antibody or antibody fragment having specific binding

affinity to the kinase polypeptide PAK5 or to a kinase domain peptide of PAK5 (see page 9, paragraphs 63-69, and claim 21 from Plowman et al.). These antibodies to PAK5 can be either monoclonal or polyclonal (see page 9, paragraphs 63-69, and claim 21 from Plowman et al.). The 398 amino acid sequence of Plowman et al., as well as antibodies to said sequence, are fully supported in their provisional application 60/081,784 filed April 14, 1998 (see additionally pages 27-28, paragraphs 350-368).

Claims 65-68 were rejected as being anticipated by Plowman et al. since an antibody that binds to the 398 amino acid sequence disclosed by Plowman et al. would necessarily bind to human PAK4, SEQ ID NO:2 of the instant application, since the 398 amino acid sequence disclosed by Plowman et al. is completely contained within, and is 100% identical to, SEQ ID NO:2 of the instant application.

Applicant has argued that this art does not meet all of the claim limitations. Specifically, applicant appears to be arguing that Plowman et al. does not anticipate the claimed invention since Plowman et al. has identified his sequence as PAK5, while the instant claims are drawn to PAK4.

This argument has been considered and is not persuasive. Antibodies bind to epitopes and not to whole proteins. Typically, between 15-22 amino acids of a protein antigen are bound by an antibody molecule (see Goldsby et al., pages 62-67, particularly page 63, the second full paragraph of the left column). Therefore, there are many shared epitopes between the 398 amino acid sequence of Plowman et al. and SEQ ID NO:2 of the instant invention. Since the structures (i.e. the amino acid sequences) of these epitopes are identical, an antibody generated against such an

epitope would necessarily bind both sequences. This is why antibodies to the human sequence disclosed by Plowman et al. also anticipate antibodies to mouse PAK4. The disclosed mouse PAK4 partial sequence (SEQ ID NO:14) is 89 amino acids long, and SEQ ID NO:14 is 96.5% similar to the 398 amino acid sequence disclosed by Plowman et al, with 85 identities, 3 conservative substitution and 1 mismatch (see enclosed search notes). The spacing of the amino acid differences easily allows for the existence of multiple shared identical sequence epitopes of between 15-22 amino acid residues. Further, new claims 69-71 are not limited to antibodies that bind SEQ ID NO:14, and as such the claimed antibodies can bind allelic variants and other sequence alterations. Since the structure of allelic variants, analogs, fragments, or derivatives of PAK4 are not clearly defined by the specification, antibodies to the 398 amino acid sequence of Plowman et al. anticipate the invention of claims 69-71.

It is noted that SEQ ID NO:2 of the instant application is longer than the 398 amino acids disclosed by Plowman et al. Antibodies that are directed to epitopes found in the sequence of PAK4 that do not align with the 398 amino acid sequence of Plowman et al. are not anticipated by the prior art. However, this subgenus of antibodies is not currently claimed, and the breadth of the current claims is anticipated by the disclosure of Plowman et al. in their provisional application 60/081,784 filed April 14, 1998.

Therefore, the prior art anticipates the claimed invention.

7. No claims are allowable.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Szperka whose telephone number is 571-272-2934. The examiner can normally be reached on M-F 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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